



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
Rockville, MD 20857

April 9, 2004

Stephen G. Juelsgaard  
Genentech, Inc.  
1 DNA Way  
San Francisco, CA 94080-4990

Dear Mr. Juelsgaard:

Your petition, requesting the Food and Drug Administration to refrain from publishing a draft guidance document setting forth standards for the "similarity" or "sameness" of biotechnology-derived products and approving an application filed under section 505(b)(2) with respect to a biotechnology-derived product that relies, directly or indirectly, on Genentech's trade secret and confidential commercial data and information, was received by this office on 04/08/2004. It was assigned docket number 2004P-0171 and it was filed on 04/08/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler  
Division of Dockets Management  
Office of Management Programs  
Office of Management

Cc: Meredith Manning  
Hogan & Hartson, LLP  
555 13th ST NW

Washington, DC 20004

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